

AMENDMENTS TO THE SPECIFICATION

Paragraph number notations refer to Applicant's published patent application US 2005/0085776 A1.

Please replace paragraph [0041] with the following amended paragraph:

[0041] The operating means for operating the dispensing means of the injection device shown in FIG. 1 is formed as a one-piece lever 7 comprising a lever arm 8 and a protrusion 9. A fulcrum 10 of the one-piece lever 7 is laterally arranged on the injection device, about in the middle with respect to the length of the injection device. The fulcrum 10 is substantially provided on the circumferential surface of the injection device. The one-piece lever 7 can be pivoted in the radial direction of the casing 3 via the fulcrum 10. Accordingly, the one-piece lever 7 can be moved towards the longitudinal axis of the injection device. In some embodiments, the lever arm 8 is preferably formed with a length corresponding to the average width of a hand. In some embodiments, the overall length of the lever may be approximately 85 mm, and the exposed length may be 63 mm, but these lengths may be varied as suitable. In some embodiments, the free end of the lever may travel approximately 6 mm, but this may be varied as suitable. In some embodiments, the force applied to the free end of the lever to actuate the device ranges between approximately 15-20 N; this force may be varied as suitable, and may depend on additional factors such as: the diameter of the needle of the device, the friction between the piston and ampule, etc.

Please replace paragraph [0043] with the following amended paragraph:

[0043] FIG. 2a shows the injection device described in FIG. 1 in a first state in which the one-piece lever 7 is in a position pivoted away from the casing 3 of the injection device. The contact point 12 between the oblique surface 11 of the protrusion 9 and the facing surface 6 of the piston rod 5 is situated in an area near the tip of the protrusion 9. A step 13 is provided on the upper side of the protrusion 9, opposite the oblique surface 11, said step pushing against an edge of the casing 3 and preventing the one-piece lever 7 from pivoting further and out of the casing

3. In the first state, the injection device is in a starting position for dispensing a dosage of the fluid product from the product container.

Please replace paragraph [0044] with the following amended paragraph:

[0044] FIG. 2b shows the injection device of FIG. 1 in a second state in which the one-piece lever 7 is pivoted or pushed in the radial direction, into the casing. The contact point 12 between the oblique surface 11 of the protrusion 9 and the facing surface 6 of the piston rod 5 lies further away from the tip of the protrusion 9 than the contact point shown in FIG. 2a. Due to the geometry of the triangle formed by the piston rod 5, the lever arm 8 and the oblique surface 11 of the protrusion 9, it is possible when pivoting the one-piece lever 7 to generate a force in the direction of the longitudinal axis of the casing, onto the outlet of the product container 1. When the one-piece lever 7 is pivoted into the casing 3, the contact point 12 slides along the oblique surface 11, which converts the movement of the protrusion 9 in the radial direction of the casing 3 into a force component in the longitudinal direction of the casing 3. Using the force component in the longitudinal direction of the casing 3, the piston rod 5 can shift the piston towards the outlet of the product container and administer a product dosage.

Please replace paragraph [0045] with the following amended paragraph:

[0045] With continued reference to FIG. 2, which includes FIGS. 2a-e, FIGS. 2c and 2d depict an embodiment wherein an activating member 17 may be provided in order to effect actuation of the dispensing mechanism upon displacement of the side lever 21 from a first position to a second, inwardly retracted position. The activating member also acts as a safety mechanism to prevent disposal of fluid product through the needle upon inadvertent displacement of, or application of force to, the side lever 21. Generally, the activating member 17 works in cooperation with the split nut 202 and split nut sleeve 204, which belong to a holding mechanism for holding or restraining parts of the dispensing mechanism as ampoules are changed, to cause selective engagement and disengagement of the split nut 202 with the threaded drive rod assembly 201, 203, 219 depending on or reflecting the radial position of the activating member 17. More particularly, in one embodiment, the activating member 17 cooperates with a coupling

sleeve which is shown in FIG. 2d generally next to the activating member 17. Referring to FIG. 2e, moving the activating member 17 from the first stop 54 to the second stop 55 results in turning the coupling sleeve, the sleeve 201, the split nut 202 and the split nut sleeve 204 on the threaded rod. The activating member 17 may include a radial projection, which also may be thought of and referred to as a releasing element 50, projecting radially outward from inside the housing 223, 224, extending through an opening 52 in the housing 223, 224. The radial projection 50 enables a user of the injection device to position the activating member 17 at a first position, wherein the radial projection 50 abuts a first stop 54, or a second position, wherein the radial projection 50 abuts a second stop 55.

Please replace paragraph [0049] with the following amended paragraph:

[0049] FIG. 3 shows a second embodiment of an injection device as set forth in the present invention, in which there is a sliding connection between the protrusion 9 of the one-piece lever 7 and the facing surface 6 of the piston rod 5. The sliding connection is formed by a T-connection formed by a T-shaped attachment 14 extending along the oblique surface 11 of the protrusion 9 and two mutually opposing hooks 15 and 16 projecting from the facing surface 6. The hooks 15 and 16 enclose the T-bar of the T-shaped attachment 14 between themselves and the facing surface 6, such that the protrusion 9 cannot be moved from the facing surface 6 in the direction of the longitudinal axis of the casing 3. In the radial direction with respect to the casing 3, however, the protrusion 9 comprising the T-shaped attachment 14 can be slid within the hooks 15 and 16. When the one-piece lever 7 is pivoted into the casing 3, therefore, the T-shaped attachment 14 slides along the facing surface 6, within the hooks 15 and 16. The oblique surface 11 of the protrusion 9 is then formed by the upper side of the T-bar of the T-shaped attachment 14.

Please replace paragraph [0050] with the following amended paragraph:

[0050] Furthermore, an indicator for indicating a product amount in the product container can be provided in an injection device as set forth in the embodiments shown in FIGS. 1 to 3. As shown in FIGS. 1 and 3, the indicator can be formed by a scale drum 317 and a window 18 in the casing

3. The scale drum 317 comprises a scale having a graduation of whole numbers of units. Furthermore, a grating 19 is provided on an exterior circumferential surface of the scale drum 317. An actuator 22 pointing radially to the longitudinal axis of the injection device is provided on the one-piece lever 7, said actuator pointing towards the scale drum 317 and co-operating with the grating 19. Another latching means 20 may be provided on a facing surface of the scale drum 317, said latching means co-operating with a complementary latching means (not shown) of a sleeve-shaped element 321 adjacent to the scale drum 317. Due to the scale drum 317 co-operating with the sleeve-shaped element 321 via the latching means 20 and the complementary latching means (not shown), the scale drum 317 is blocked against rotating in one direction, whereas it remains possible for it to rotate in the opposite direction.

Please replace paragraph [0051] with the following amended paragraph:

[0051] FIG. 4a shows the injection device in the first state as set forth in FIG. 2a, in a cross-section. Accordingly, the injection device is in a starting position for administering a product dosage, in which the one-piece lever 7 is in a position pivoted away. The actuator 22 engages, via its front tip, with the grating 19 of the scale drum 317. FIG. 4b shows the injection device in a second position as set forth in FIG. 2b, in which the one-piece lever 7 is in a position pivoted in. When the lever is pivoted, the actuator 22 is shifted in the radial direction into the casing 3 together with the one-piece lever 7, which causes the scale drum to rotate since the actuator 22 pushes against the grating in the rotational direction of the scale drum 317. During a pivoting movement, the scale drum 317 is preferably rotated on by a distance corresponding to the distance between two scale units on the scale drum. It is therefore possible to rotate the scale drum on by one unit with every administering, i.e., with each pivoting of the lever. Preferably, the scale drum counts from a highest numerical value to a lowest numerical value, such that the dosage units remaining in the product container can be read from the indicator. When the one-piece lever 7 is pivoted back out of the casing 3 of the injection means, the actuator 22 is pulled across the grating 19, since the tip of the actuator 22 can slide over a bevel of the grating. Also, the scale drum 317 is fixed in an opposite rotational direction by the latching means 20 and the complementary latching means (not shown) of the adjacent sleeve-shaped element 321.